Restrictions on veterinary medicine use to prevent/eradicate animal diseases

Published by AGRINFO on 23 Nov 2022; Revised 15 Mar 2023

EU rules on vaccines and veterinary medicines to prevent and control animal diseases subject to compulsory eradication, and on follow-up

Commission Delegated Regulation (EU) 2023/361 of 28 November 2022 supplementing Regulation (EU) 2016/429 of the European Parliament and the Council as regards rules for the use of certain veterinary medicinal products for the purpose of prevention and control of certain listed diseases

Update

Aiming to prevent the most devastating animal diseases (category A and B diseases), this Regulation harmonises within the EU the use of certain vaccines and veterinary medicinal products that prevent and control diseases. The objective is to eradicate the diseases and prevent any risk of their spread through the use of veterinary drugs (for example, certain drugs may mask some diseases; vaccinated animals may spread a virus).

Impacted products

terrestrial and aquatic animals

What is changing?

In the framework of rules for prevention and control of listed diseases in kept and wild terrestrial and aquatic animals (Animal Health Law, Regulation (EU) 2016/429), this Regulation foresees that:

- Member States may allow, under certain conditions, the use of vaccines in animals for the prevention and control of category A diseases except for infection with rinderpest virus.
- Vaccines against Newcastle disease can be used for disease prevention, including for trade.
- Member States may allow the use of vaccines in animals for the prevention and control of category B diseases except for infections with Mycobacterium tuberculosis complex (M. bovis, M. caprae and M. tuberculosis).

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- Bruceline can be used to diagnose the state of immunity of animals in cases of infection with Brucella abortus, B. melitensis and B. suis.
- Tuberculine can be used to diagnose the state of immunity of animals in cases of infection with Mycobacterium tuberculosis complex.
- The use of veterinary medicinal products other than vaccines is forbidden for the prevention and control of category A and B diseases, except those used for prevention and control of the diseases listed in Annex I, Part 3. These include immunological veterinary medicinal products to diagnose the state of animals' immunity (brucelin, tuberculin), hyper-immune serum, inactivated immunological veterinary medicinal products, and antimicrobials.
- Member States can use vaccines in animals for category A diseases only under certain conditions, such as an assessment and a vaccination plan. A vaccination strategy is proposed, together with surveillance measures (Art. 7–11). Some disease-specific conditions of vaccination are foreseen in the Annex for foot and mouth disease (FMD); Rift Valley fever virus (RVFV); lumpy skin disease virus (LSDV); peste des petits ruminants virus (PPR); African horse sickness (AHS); classical swine fever (CSF); highly pathogenic avian influenza (HPAI); and Newcastle disease virus (NDV).
- Member States have to adopt risk-mitigating measures to prevent the spread of category A diseases through vaccinated animals or products from such animals (Arts. 12–16).

Why?

The aim of the new Regulation is to supplement the Animal Health Law (Regulation (EU) 2016/429) on the prevention and control of animal diseases, in order to take account of newly available scientific knowledge, experience gained, and international standards. The EU considers that harmonising these rules at EU level will reinforce efforts to eradicate category A and B diseases.

Timeline

Date of publication: 20 February 2023.

Date of application: 12 March 2023.

What are the major implications for exporting countries?

The new Regulation applies to production within the EU. Animal health requirements for countries exporting to the EU are covered by Regulation 2020/692.

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Background

- The Animal Health Law, Regulation (EU) 2016/429, is the basic act laying down rules for the prevention and control of animal diseases that are transmissible to animals or to humans, including rules on disease awareness, preparedness and control.
- Implementing Regulation (EU) 2018/1882 lays down the definitions of category A, B, C, D and E diseases, relying on disease prevention and control rules set out in Article 9(1) of Regulation (EU)2016/429.
- Category A diseases are those that do not normally occur in the EU, and for which immediate eradication measures are to be taken as soon as they are detected.
- Category B diseases are those which are to be controlled in all EU Member States, with the goal of eradicating them throughout the EU.
- With a view to preventing potentially devastating effects of category A and B diseases, the use of vaccines and veterinary medicinal products for the prevention and control of those diseases needs to be harmonised.

Resources

European Commission (n.d.) Animal Health Law: Key to the prevention and control of diseases in your animals.

Sources

Delegated Regulation (EU) 2023/361

Regulation (EU) 2016/429

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